DETAILED ACTION

Applicants response filed May 31, 2011 has been received and entered. Claims 3-4, 9-10, 13-16, 18, and 22-23 have been cancelled. Accordingly, claims 1-2, 5-8, 11-12, 17, 19-21, and 24-30 are pending in the instant application, of which claims 1-2, 5-8, 11-12, 17, 19-21, and 24-28 have been withdrawn from further consideration as being drawn to a non-elected invention.

Specification

1. The objection to the specification for reciting a sequence of greater than 10 nucleotides and failing to have a sequence identifier is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. The rejection of claims 29-30 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al in light of Murasugi et al is maintained.

Applicants are asserting that the nucleotide SEQ ID NO: 1 as recited in claim 29 is NOT the same as the amino acid sequence disclosed in Murasugi, even though SEQ ID NO: 1 will encode the same amino acid as Murasugi. Applicants have further shown that SEQ ID NO: 1 (modified FIP nucleotide codon) and SEQ ID NO: 2 (original wild type Ling-Zhi-8 nucleotide codon) have different sequences.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants assert that the nucleotide SEQ ID NO: 1 as recited in claim 29 is NOT the same as the amino acid sequence disclosed in Murasugi, even though SEQ ID NO:

1 will encode the same amino acid as Murasugi. This statement is readily agreed upon as a nucleic acid sequence and a protein sequence can never be the same (DNA comprises nucleotides and protein comprises amino acids). However, Applicants are respectfully directed to their own claim language which recites "A method of modulating immunological activities comprising orally administering **fungal immunomodulatory protein** or protein fused with FIP to a subject, **wherein the fungal immunomodulatory protein is encoded by a nucleic acid molecule including SEQ ID NO: 1**." (Emphasis added). As Applicants have acknowledged "SEQ ID NO: 1 will decode the same amino acid as Murasugi." (Response page 7). This is precisely what is required by Applicants claims, administration of a fungal immunomodulatory protein encoded by SEQ ID NO: 1. The claims require the administration of a protein, NOT a DNA molecule. As a hypothetical example, if Applicants claims recited "A method comprising the following steps: transfecting a yeast host cell with the nucleic acid sequence comprising SEQ ID NO:1, expressing the recombinant protein, isolating the protein, and administering the isolated protein to a subject" then yes, SEQ ID NO: 1 would have to be taught or suggested by the art to anticipate or render obvious such a claim. Applicants instant claims are distinguished from such a hypothetical claim in that it encompasses the administration of any fungal immunomodulatory protein encoded by SEQ ID NO: 1, or any protein encoded by any degenerate variant of SEQ ID NO: 1, as each and every degenerate variant will encode the exact identical protein, thereby meeting each and every limitation of the instantly filed claims. NOTE: the above hypothetical claim is not to be construed as allowable subject matter, as no search of

support within Applicants specification or art teaching of optimizing yeast codon usage has been performed.

The claims are directed to a method of modulating immunological activities comprising orally administering fungal immunomodulatory protein or protein fused with FIP to a subject, wherein the fungal immunomodulatory protein is encoded by a nucleic acid molecule including SEQ ID NO: 1.

Evans et al (US Patent Number 5,928,896) disclose of compositions of immunomodulatory peptides comprising Ling-Zhi-8 for oral administration. (See Immunomodulator peptides section).

Murasugi et al (Journal of Biological Chemistry Vol. 256, No. 4, pp 2486-2593, 1991) disclose of the amino acid sequence of Ling-Zhi-8. (See page 2489).

SEQ ID NO: 1 of the instant invention encodes with 100% identity the Ling Zhi-8 protein. Accordingly, the disclosure of Evans et al of a composition for oral administration comprising the Ling Zhi-8 protein (protein encoded by a nucleic acid molecule including SEQ ID NO: 1) is deemed to anticipate each and every limitation of the instantly filed claims.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571)272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
June 10, 2011